

HERC Coverage Guidance – Continuous Glucose Monitoring in Diabetes Mellitus Disposition of Public Comments – Second Posting

General Comments

Stakeholder	#	Comment	Disposition
<p><i>American Diabetes Association</i> Oregon Office Portland, OR</p>	1	<p>On behalf of the people with diabetes in Oregon, the American Diabetes Association (Association) is pleased to provide additional comments to the Commission regarding the revised <i>Draft Coverage Guidance on Continuous Glucose Monitoring (CGM) in Diabetes Mellitus</i>.</p> <p>The Association’s <i>Standards of Medical Care in Diabetes – 2012</i> includes the following recommendations:</p> <ul style="list-style-type: none"> • CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults age 25 and over with type 1 diabetes. • Although the evidence for A1c-lowering is less strong in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. • In addition, CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. 	<p>Thank you for taking the time to comment. HTAS is aware of ADA recommendations.</p>
	2	<p>The revised <i>Draft Coverage Guidance on Continuous Glucose Monitoring in Diabetes Mellitus</i> issued on September 24 includes the following recommendation: Real time CGM systems should be covered for Type 1 diabetes mellitus patients with HbA1c > 8% or a history of recurrent hypoglycemia or for whom insulin pump management is being considered, initiated or utilized, and should not be covered for individuals with type 2 diabetes mellitus. Research has shown benefits for CGM in individuals with type 1 diabetes on intensive insulin therapy, through <i>either</i> an insulin pump or multiple daily injections.¹ <i>As such, we recommend anyone on multiple doses of insulin or continuous subcutaneous insulin infusion with recurrent hypoglycemic episodes or persistently high HbA1c levels be given the option of real-time CGM.</i></p> <p>¹Tamborlane WV, Beck RW, Bode BW, et al.; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. <i>N Engl J Med</i> 2008;359:1464-1476.</p>	<p>The citations listed were published before the date of both evidence reviews (last search dates June and July 2011). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions. Both evidence sources found significantly greater improvement in HbA1c in patients using insulin pumps than in those using multiple daily injections,</p>

HERC Coverage Guidance – Continuous Glucose Monitoring in Diabetes Mellitus Disposition of Public Comments – Second Posting

Stakeholder	#	Comment	Disposition
	3	<p>Diabetes is a complex disease to manage and can lead to short and long term complications. The goal of diabetes care is to avoid the devastating and costly complications of the disease. The costs associated with diabetes, including diagnosed and undiagnosed diabetes, prediabetes, and gestational diabetes, and their complications, accounted for \$218 billion in direct and indirect costs in 2007 alone. Much of the economic burden of diabetes is related to its complications including blindness, amputation, kidney failure, heart attack, and stroke. Yet, we have made major strides in effectively managing diabetes and reducing the risk for these devastating – and costly – complications through necessary medical care, medications and other tools, patient self-management, education, and support. We appreciate the opportunity to provide comments to the Commission as it develops the Coverage Guidance document for CGM.</p>	<p>and no difference in risk of severe hypoglycemia.</p> <p>HTAS is aware of the implications and costs of diabetes. Thank you for your comment.</p>